

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Mantelle et al.

Title: Compositions and Methods for Treatment
of Attention Deficit Disorder and Attention
Deficit/Hyperactivity Disorder with
Methylphenidate

Appl. No.: 10/024,513

Filing Date: December 21, 2001

Examiner: Frank I. Choi

Art Unit: 1616

DECLARATION UNDER 37 C.F.R. §1.131

Commissioner for Patents
Washington, D.C. 20231

Sir:

1. This Declaration is submitted to establish completion of the invention in this application in the United States, on a date before February 15, 2001, which I am told is the effective prior art date of WO 01/10420 (hereinafter "Vickers") under § 102(a)/103(a) of the patent laws. I understand that Vickers was cited by the Examiner in an Office Action dated December 15, 2003 in the above-identified application. The person making this declaration is one of the two joint inventors of the above-referenced application.

FACTS AND DOCUMENTARY EVIDENCE

2. The attached Plasma Profiles (Exhibit 1) are submitted as evidence that the invention claimed in this application was actually reduced to practice prior to February 15, 2001.

3. All the dates have been deleted from Exhibit 1 to preserve the actual reduction to practice date in confidence. However, the Declarant certifies that a clinical study was performed, the results analyzed and graphs prepared earlier than February 15, 2001.
4. The Exhibits demonstrates that a composition that delivers methylphenidate in an amount and rate sufficient to increase the methylphenidate plasma concentration of a subject being treated over a period of about 6-16 hours, followed by a steady decrease in the plasma concentration of methylphenidate was reduced to practice before February 15, 2001.
5. The examples that were actually reduced to practice and described in Exhibit 1 correspond to Example 1 and Figures 1 and 2 of the present application. Therefore, Declarants believe that they were in possession of the whole invention or data/information falling within the claims before February 15, 2001.
6. Vickers was published on February 15, 2001. The invention set forth in claims 1-5, 7-14, 16-23, 25-32, and 34-42 of the present application was conceived prior to February 15, 2001 and we were diligent in working toward reducing the invention to practice at least until December 21, 2001, the filing date of the above-referenced application.

CONCLUSION

7. The attached exhibits provide evidence of the actual reduction to practice of the invention in this application before February 15, 2001. Each of the dates deleted from Exhibit 1 is earlier than February 15, 2001.

8. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 7/27/04

Respectfully submitted,

By:

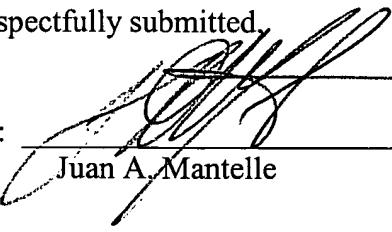

Juan A. Mantelle



Figure1 Mean (linear) *d*-MPH plasma profiles in 29 subjects on Day 6 after administering 25cm² MTS units every 24 h (MTS) for 16 h or 20 mg oral Ritalin® at 7 AM, 11 AM and 3 PM daily (Ritalin®).

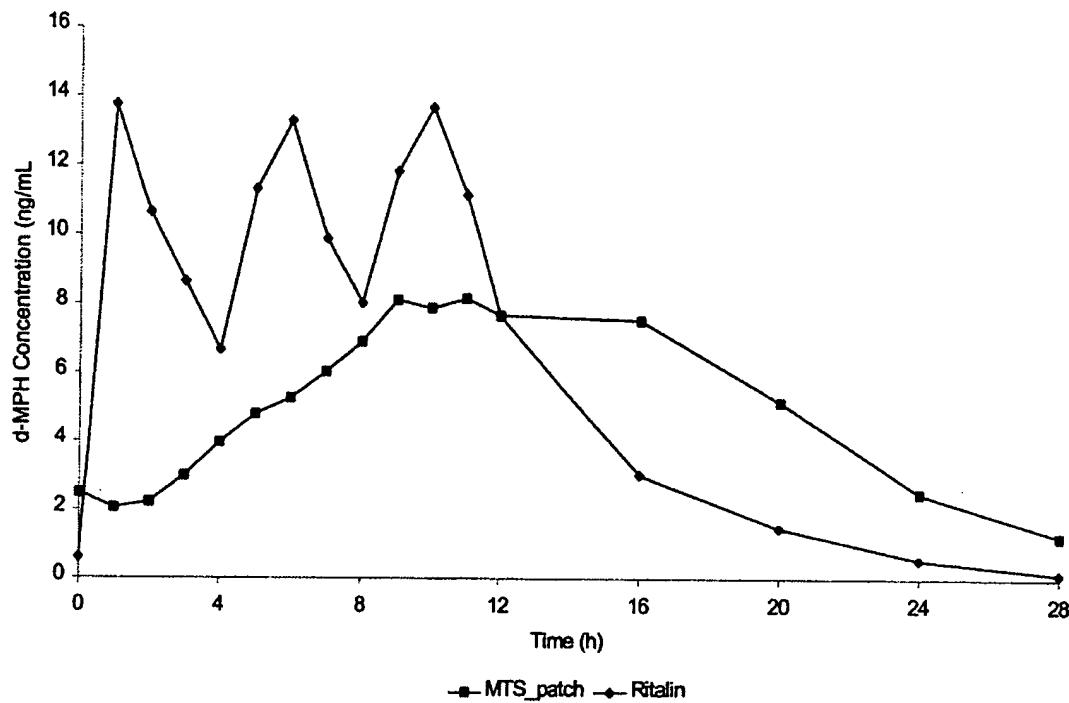




Figure 2 Mean (linear) *L*-MPH plasma profiles in 29 subjects on Day 6 after administering 25cm² MTS units every 24 h (MTS) for 16 h or 20 mg oral Ritalin® at 7 AM, 11 AM and 3 PM daily (Ritalin®).

